genus, *Mucor;* species, *miehei;* variety *Cooney et Emerson*.

(b) The strain of *Mucor miehei* var. *Cooney et Emerson* is nonpathogenic and nontoxic in man or other animals.

(c) The enzyme is produced by a process which completely removes the organism *Mucor miehei* var. *Cooney et Emerson* from the esterase-lipase.

(d) The enzyme is used as a flavor enhancer as defined in §170.3(o)(12).

(e) The enzyme is used at levels not to exceed current good manufacturing practice in the following food categories: cheeses as defined in §170.3(n)(5) of this chapter; fat and oils as defined in §170.(3)(n)(12) of this chapter; and milk products as defined in §170.(3)(n)(31) of this chapter. Use of this food ingredient is limited to nonstandarized foods and those foods for which the relevant standards of identity permit such use.

(f) The enzyme is used in the minimum amount required to produce its limited technical effect.

[47 FR 28090, June 29, 1982; 48 FR 2748, Jan. 21, 1983]

### § 173.145 Alpha-Galactosidase derived from *Mortierella vinaceae* var. *raffinoseutilizer*.

The food additive alpha-galactosidase and parent mycelial microorganism *Mortierella vinaceae* var. *raffinoseutilizer* may be safely used in food in accordance with the following conditions:

(a) The food additive is the enzyme alpha-galactosidase and the mycelia of the microorganism *Mortierella vinaceae* var. *raffinoseutilizer* which produces the enzyme.

(b) The nonpathogenic microorganism matches American Type Culture Collection (ATCC) No. 20034,[1] and is classified as follows:

Class: Phycomycetes.
Order: Mucorales.
Family: Mortierellaceae.
Genus: *Mortierella*.
Species: *vinaceae*.
Variety: *raffinoseutilizer*.

(c) The additive is used or intended for use in the production of sugar (sucrose) from sugar beets by addition as mycelial pellets to the molasses to increase the yield of sucrose, followed by removal of the spent mycelial pellets by filtration.

(d) The enzyme removal is such that there are no enzyme or mycelial residues remaining in the finished sucrose.

[42 FR 14526, Mar. 15, 1977, as amended at 54 FR 24897, June 12, 1989]

### § 173.150 Milk-clotting enzymes, microbial.

Milk-clotting enzyme produced by pure-culture fermentation process may be safely used in the production of cheese in accordance with the following prescribed conditions:

(a) Milk-clotting enzyme is derived from one of the following organisms by a pure-culture fermentation process:

(1) *Endothia parasitica* classified as follows: Class, Ascomycetes; order, Sphaeriales; family, Diaporthacesae; genus, *Endothia;* species, *parasitica*.

(2) *Bacillus cereus* classified as follows: Class, Schizomycetes; order, Eubacteriales; family, Bacillaceae; genus, *Bacillus;* species, *cereus* (Frankland and Frankland).

(3) *Mucor pusillus* Lindt classified as follows: Class, Phycomycetes; subclass, Zygomycetes; order, Mucorales; family, Mucoraceae; genus, *Mucor;* species, *pusillus;* variety, *Lindt*.

(4) *Mucor miehei Cooney et Emerson* classified as follows: Class, Phycomycetes; subclass, Zygomycetes; order, Mucorales; family, Mucoraceae; genus, *Mucor;* species, *miehei;* variety, *Cooney et Emerson*.

(5) *Aspergillus oryzae* modified by recombinant deoxyribonucleic (DNA) techniques to contain the gene coding for aspartic proteinase from *Rhizomucor miehei* var. *Cooney et Emerson* as defined in paragraph (a)(4) of this section, and classified as follows: Class, Blastodeuteromycetes (Hyphomycetes); order, Phialidales (Moniliales); genus, *Aspergillus*; species *oryzae*.

(b) The strains of organism identified in paragraph (a) of this section are nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that completely removes the generating organism from the milk-clotting enzyme product.

[1] Available from: American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD 20852.

(d) The additive is used in an amount not in excess of the minimum required to produce its intended effect in the production of those cheeses for which it is permitted by standards of identity established pursuant to section 401 of the Act.

[42 FR 14526, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 62 FR 59284, Nov. 3, 1997]

### § 173.160 *Candida guilliermondii.*

The food additive *Candida guilliermondii* may be safely used as the organism for fermentation production of citric acid in accordance with the following conditions:

(a) The food additive is the enzyme system of the viable organism *Candida guilliermondii* and its concomitant metabolites produced during the fermentation process.

(b)(1) The nonpathogenic and nontoxicogenic organism descending from strain, American Type Culture Collection (ATCC) No. 20474,[1] is classified as follows:

Class: Deuteromycetes.
Order: Moniliales.
Family: Cryptococcaceae.
Genus: *Candida*.
Species: *guilliermondii*.
Variety: *guilliermondii*.

(2) The toxonomic characteristics of the reference culture strain ATCC No. 20474 agree in the essentials with the standard description for *Candida guilliermondii* variety *guilliermondii* listed in ''The Yeasts—A Toxonomic Study;'' 2d Ed. (1970), by Jacomina Lodder, which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

[1] Available from: American Type Culture Collection, 12301 Parklawn Drive, Rockville, MD 20852.

(c)(1) The additive is used or intended for use as a pure culture in the fermentation process for the production of citric acid using an acceptable aqueous carbohydrate substrate.

(2) The organism *Candida quilliermondii* is made nonviable and is completely removed from the citric acid during the recovery and purification process.

(d) The additive is so used that the citric acid produced conforms to the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), under ''Citric acid,'' pp. 86–87, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

[42 FR 14526, Mar. 15, 1977, as amended at 47 FR 11838, Mar. 19, 1982; 49 FR 10106, Mar. 19, 1984; 54 FR 24897, June 12, 1989]

### § 173.165 *Candida lipolytica.*

The food additive *Candida lipolytica* may be safely used as the organism for fermentation production of citric acid in accordance with the following conditions:

(a) The food additive is the enzyme system of the organism *Candida lipolytica* and its concimitant metabolites produced during the fermentation process.

(b)(1) The nonpathogenic organism is classified as follows:

Class: Deuteromycetes.
Order: Moniliales.
Family: Cryptococcaceae.
Genus: *Candida*.
Species: *lipolytica*.

(2) The taxonomic characteristics of the culture agree in essential with the standard description for *Candida lipolytica* variety *lipolytica* listed in ''The Yeasts—A Toxonomic Study,'' 2d Ed. (1970), by Jacomina Lodder, which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park,